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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/612,661	03/08/96	CHRISTENSEN L	1515 2165

18N2/1203

JOHN W CALDWELL
WOODCOCK WASHBURN KURTZ MACKIEWICZ
AND NORRIS
ONE LIBERTY PLACE - 46TH FLOOR
PHILADELPHIA PA 19103

EXAMINER	
MARSCHEL, A	
ART UNIT	**PAPER NUMBER**
1809	

DATE MAILED: 12/03/96

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Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

Office Action Summary

Application No.	Applicant(s)
08/612,661	Christensen et al.
Examiner	**Group Art Unit**
Ardin Marschel	1809

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-10 is/are pending in the application.

Of the above, claim(s) 9 and 10 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-8 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, ~~Paper No(s).~~ 2 sheets

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☒ Summary of CRF sequence listing errors

--- *SEE OFFICE ACTION ON THE FOLLOWING PAGES* ---

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-8, drawn to nucleic acid mimics containing bases with sterically bulky substituents, classified in Class 536, subclass 23.1.

II. Claim 9, drawn to a method of determination of a nucleic acid, classified in Class 435, subclass 6.

III. Claim 10, drawn to a compound for the preparation of nucleic acid mimics, classified in Class 536, subclass 22.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I or its synthesis via the Group III monomers and Group II are related as product or materials for making said product and a process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the product of Group I, including synthesized via Group III can be used in the materially different process of antisense therapy as distinct from hybridization type assays of Group II.

Inventions of Group I and Group III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as

claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations. (M.P.E.P. § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination of Group I can be prepared either as monomers linked together or as oligomers linked together or alternatively the the oligomers of Group I may be prepared without utilizing the Group III monomers by utilizing variously protected monomers that are not of the Group III type, deprotecting and lastly modifying with the sterically bulky groups. The subcombination has separate utility such as monomers that are themselves inhibitory to enzymatic reactions that utilize nucleotides or nucleotide analogs as either substrates or cofactors.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

During a telephone conversation with John Caldwell on 10/25/96 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-8. Affirmation of this election must be made by applicant in responding to this Office action. Claims 9 and 10 are withdrawn from further

consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR § 1.821 through 1.825 because the computer readable form contains errors as summarized on the sequence error listing enclosed with this office action. Applicants are given the same response time regarding this failure to comply as that set forth to respond to this office action.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to nucleic acid mimics that are formable via either peptide bond type linkages or vinyl polymerization type linkages. Consideration of the instant specification reveals that the only chemistry that is described is the linking of monomers into nucleic acid polymers via peptide bond formation chemistry. It is however noted that vinyl monomeric type polymerization methods with nucleic acid bases as side groups is well known in the art

to make nucleic acid mimics. Since the nucleotide bases are very reactive and must be protected during polymerization reactions with protective groups, that protect amines, for example; the determination of synthetic pathways that maintain these protective groups during polymerization and permit their removal after said polymerization without hydrolyzing the backbone is complex. This complexity results in undue experimentation for syntheses of backbones other than of those types that are either well known in the art or described in significant detail in the instant specification. See M.P.E.P. §§ 706.03(n) and 706.03(z).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Summerton et al.

Summerton et al. (WO 86/05518) disclose the preparation of nucleic acid mimics that have a non-natural backbone PNA type backbone with nucleotide bases as side groups that have attached sterically bulky groups within the instant invention definitions that are also at least 3 atoms away from the base attachment position. For example, on page 21, lines 2-9, N2 of Guanosine and N4 of cytosine are listed as having protective groups that

are bulky as instantly claimed and more than 3 atoms away from the linkage to the backbone. These groups are present during synthesis but it is noted that the instant claims are not limited such that synthetic forms are excluded. The benzoyl group on the N4 of cytosine in a PNA polymer as cited on said page 21 clearly reads on instant claim 8, for example.

The disclosure is objected to because of the following informalities:

On page 17, line 25, of the specification the word "Phsphoramidates" appears to be misspelled.

Appropriate correction is required.

No claim is allowed.

Papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1800 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 305-7401 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Elliot, can be reached on (703) 308-4003.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

November 25, 1996

Ardin H. Marschel

ARDIN H. MARSCHEL
PATENT EXAMINER
GROUP 1800